UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JANET FEARRINGTON, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	CASE No.: _____ COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL 1. Strict Liability – Failure to Warn 2. Strict Liability – Manufacturing Defect 3. Strict Liability – Design Defect 4. Negligence 5. Breach of Implied Warranty 6. Breach of Express Warranty 7. Fraud 8. Negligent Misrepresentation 9. Fraud by Concealment

Plaintiff, for her causes of action against the Defendant, alleges as follows:

INTRODUCTION

1. On February 21, 2006, Plaintiff, JANET FEARRINGTON, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx") and polyform synthetic mesh, a medical device designed and manufactured by the Defendant, Boston Scientific Corporation ("Boston Scientific"). Although the system was intended to treat urinary incontinence, neither Plaintiff nor her healthcare providers were warned that the Obtryx was negligently designed and manufactured. Indeed, on June 26, 2017, Plaintiff had second Boston Scientific transvaginal mesh device implanted in her, the Boston Scientific Advantage Fit System ("Advantage Fit"), to treat her urinary incontinence. Neither Plaintiff nor her healthcare providers were warned that the Obtryx and the Advantage Fit were unreasonably dangerous, even when used exactly as intended by Boston Scientific. To the contrary, Boston Scientific promoted, marketed and sold the type of transvaginal mesh devices implanted in Plaintiff (and

thousands of women like Plaintiff) to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendant's products. As a result of being surgically implanted with Defendant's unreasonably dangerous transvaginal mesh devices, Plaintiff has suffered, and continues to suffer, debilitating injuries. Plaintiff brings this suit for damages related to those injuries.

PARTIES

2. Plaintiff JANET FEARRINGTON is a citizen and resident of Livingston, Texas.

3. Defendant Boston Scientific is a Massachusetts corporation with its principal place of business in Massachusetts. At all times material hereto, Boston Scientific was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including Texas, either directly or indirectly, its medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse.

JURISDICTION AND VENUE

4. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000.00 and the Plaintiff is a citizen of a different state than the Defendant.

5. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district.

6. Defendant is subject to *in personam* jurisdiction in the U.S. District Court for the Southern District of Texas because it placed a defective product in the stream of commerce and

that product caused personal injuries to Plaintiff JANET FEARRINGTON at her residence in the State of Texas.

FACTUAL BACKGROUND

7. Defendant Boston Scientific promotes its medical devices as devices intended to treat stress urinary incontinence and/or pelvic organ prolapse.

8. Defendant Boston Scientific designed, manufactured, packaged, labeled, marketed, sold, and distributed the Obtryx Sling, the Advantage Fit Retropubic Sling, and the Polyform Synthetic Mesh ("the Products") which were implanted in Plaintiff JANET FEARRINGTON.

9. Defendant's pelvic mesh products, including the Products, contain monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with pelvic mesh products, including the Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

10. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including Defendant, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, Defendant sells pelvic mesh

"kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Boston Scientific Obtryx sling and Advantage Fit sling manufactured by Defendant are considered a Class II medical device. The Boston Scientific Polyform Synthetic Mesh product for transvaginal repair of pelvic organ prolapse has been ordered off the market after the April 16, 2019, FDA Practice Advisory.

11. Defendant sought and obtained FDA clearance to market the Obtryx and Advantage Fit under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to the Obtryx sling nor Advantage Fit.

12. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" (emphasis in the original).

13. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in the original).

14. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

15. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

16. The injuries of Plaintiff, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

17. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

18. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

19. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional

POP repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

20. The FDA White Paper further stated that, "these products are associated with serious adverse events…compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

21. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

22. As is known to the Defendant, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

23. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

24. Defendant did not, and has not, adequately studied the extent of the risks associated with the Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

25. Defendant did not, and has not, adequately studied the extent of risks associated with the Products. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

26. Defendant knew or should have known about the Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that banned the sales of transvaginal mesh implants for pelvic organ prolapse.

27. Defendant knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

28. The scientific evidence shows that the material from which the Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including Plaintiff JANET FEARRINGTON.

29. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

30. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 6/18/2019).

as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

31. The Products were unreasonably susceptible to shrinkage and contraction inside the body. Defendant should have known of this serious risk related to shrinkage and contraction of their permanent synthetic vaginal mesh products and warned physicians and patients.

32. The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

33. To this day, the Obtryx sling and the Advantage Fit Retropubic sling have been and continue to be marketed to the medical community and to patients as safe, effective, reliable medical devices, implanted by safe and effective minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of stress urinary incontinence, such as use of native tissue, and other competing products.

34. A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure") or the use of autologous slings. SUI can also be surgically addressed using autologous slings placed under the urethra to provide support. POP can be corrected through abdominal surgery and using autologous tissue, biologic, composite, or synthetic materials.

35. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Obtryx and Advantage Fit sling, and advertised, promoted, marketed, sold and distributed the Obtryx and Advantage Fit sling as safe medical devices when Defendant knew or should

have known that the Obtryx and Advantage Fit were not safe for their intended purposes, and that the Obtryx and Advantage Fit would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Obtryx and Advantage Fit slings were made known to physicians, the magnitude, severity and frequency of these problems were not disclosed and were hidden from physicians.

36. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Polyform Synthetic Mesh, and advertised, promoted, marketed, sold and distributed the Polyform Synthetic Mesh as a safe medical device when Defendant knew or should have known that the Polyform Synthetic Mesh was not safe for its intended purposes, and that the Polyform Synthetic Mesh would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Polyform Synthetic Mesh were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

37. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Obtryx and Advantage Fit have high rates of failure, injury, and complications, fail to perform as intended, requires frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

38. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Polyform Synthetic Mesh has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations,

and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

39. The specific nature of the Obtryx sling's defects includes, but is not limited to, the following:

a. The use of polypropylene in the Obtryx sling and the immune reactions that result from such material, causing adverse reactions and injuries;

b. The design of the Obtryx sling to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Obtryx sling, including, but not limited to, the propensity of the Obtryx sling to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Obtryx sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. The procedure to place the Obtryx sling requires blindly placing the arms of the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, contribute to mobility, contribute to bowel and bladder function;

f. The propensity of the Obtryx for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

g. The inelasticity of the Obtryx sling, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain

upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, walking);

h. The propensity of the Obtryx sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

i. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

40. The Obtryx sling is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Obtryx's propensities to contract, retract, and/or shrink inside the body;

b. The Obtryx's propensities for degradation, fragmentation, and/or creep;

c. The Obtryx's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Obtryx;

f. The risk of chronic infections resulting from the Obtryx;

g. The risk of permanent vaginal or pelvic scarring as a result of the Obtryx;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Obtryx;

i. The need for corrective or revision surgery to adjust or remove the Obtryx;

j. The severity of complications that could arise as a result of implantation of the Obtryx sling;

k. The hazards associated with the Obtryx sling;

l. The Obtryx's defects described herein;

m. Treatment of stress urinary incontinence with the Obtryx is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Obtryx exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Obtryx sling makes future surgical repair more difficult than the feasible available alternatives;

p. Use of the Obtryx puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Obtryx due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Obtryx may not be possible and may not result in complete resolution of the complications, including pain.

41. Defendant under reported and continues to underreport information about the propensity of the Obtryx to fail and to cause injuries, and complications, and have made unfounded representations regarding the efficacy and safety of the Obtryx through various means and media.

42. The specific nature of the Obtryx sling's defects includes, but is not limited to, the following:

a. The use of polypropylene in the Obtryx sling and the immune reactions that result from such material, causing adverse reactions and injuries;

b. The design of the Obtryx sling to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Obtryx sling, including, but not limited to, the propensity of the Obtryx sling to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Obtryx sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. The procedure to place the Obtryx sling requires blindly placing the arms of the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, contribute to mobility, contribute to bowel and bladder function;

f. The propensity of the Obtryx for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

g. The inelasticity of the Obtryx sling, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, walking);

h. The propensity of the Obtryx sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

i. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

43. The Advantage Fit sling is defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Advantage Fit's propensities to contract, retract, and/or shrink inside the body;

b. The Advantage Fit's propensities for degradation, fragmentation, and/or creep;

c. The Advantage Fit's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Advantage Fit;

f. The risk of chronic infections resulting from the Advantage Fit;

g. The risk of permanent vaginal or pelvic scarring as a result of the Advantage Fit;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Advantage Fit;

i. The need for corrective or revision surgery to adjust or remove the Advantage Fit;

j. The severity of complications that could arise as a result of implantation of the Advantage Fit sling;

k. The hazards associated with the Advantage Fit sling;

l. The Advantage Fit's defects described herein;

m. Treatment of stress urinary incontinence with the Advantage Fit is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Advantage Fit exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Advantage Fit sling makes future surgical repair more difficult than the feasible available alternatives;

p. Use of the Advantage Fit puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Advantage Fit due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Advantage Fit may not be possible and may not result in complete resolution of the complications, including pain.

44. Defendant underreported and continues to underreport information about the propensity of the Advantage Fit to fail and to cause injuries, and complications, and have made unfounded representations regarding the efficacy and safety of the Advantage Fit through various means and media.

45. The Polyform Synthetic Mesh is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Polyform Synthetic Mesh's propensities to contract, retract, and/or shrink inside the body;

b. The Polyform Synthetic Mesh's propensities for degradation, fragmentation, and/or creep;

c. The Polyform Synthetic Mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Polyform Synthetic Mesh;

f. The risk of chronic infections resulting from the Polyform Synthetic Mesh;

g. The risk of permanent vaginal or pelvic scarring as a result of the Polyform Synthetic Mesh;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Polyform Synthetic Mesh;

i. The need for corrective or revision surgery to adjust or remove the Polyform Synthetic Mesh;

j. The severity of complications that could arise as a result of implantation of the Polyform Synthetic Mesh;

k. The hazards associated with the Polyform Synthetic Mesh sling;

l. The Polyform Synthetic Mesh's defects described herein;

m. Treatment of pelvic organ prolapse with the Polyform Synthetic Mesh is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse with the Polyform Synthetic Mesh exposes patients to greater risk than feasible available alternatives;

o. Treatment pelvic organ prolapse with the Polyform Synthetic Mesh makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Polyform Synthetic Mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Polyform Synthetic Mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Polyform Synthetic Mesh may not be possible and may not result in complete resolution of the complications, including pain.

46. Defendant underreported and continues to underreport information about the propensity of the Polyform Synthetic Mesh to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

47. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Polyform Synthetic Mesh used for transvaginal pelvic organ prolapse repair.

48. Defendant failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe and effective procedure for removal of the Products exists.

49. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

50. The Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

51. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

52. The Products implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

53. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia

(pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, pudendal nerve damage, obturator nerve damage, pelvic floor damage, and chronic pelvic pain.

54. In many cases, including Plaintiff's, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

55. The medical and scientific literature studying the effects of mesh products like the Products, like that of the product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to mesh products.

56. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

57. At all relevant times herein, Defendant continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

58. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

59. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

60. The Products as designed, manufactured, distributed, sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

61. Plaintiff, JANET FEARRINGTON, was implanted with the Obtryx Sling System and Polyform Synthetic Mesh on or about February 21, 2006, in Titusville, FL, and implanted with the Advantage Fit sling on or about June 26, 2017, in Houston, TX, which were designed, manufactured, packaged, labeled, distributed and sold by Defendant Boston Scientific.

62. The Obtryx sling and the Advantage Fit sling were intended to treat Plaintiff for stress urinary incontinence, the use for which Defendant marketed the product.

63. The Polyform Synthetic Mesh intended to treat pelvic organ prolapse, the use for which Defendant marketed the product.

64. Plaintiff's treating physicians implanted the Obtryx and Advantage Fit properly and appropriately.

65. Plaintiff's treating physicians implanted the Polyform Synthetic Mesh properly and appropriately.

66. The Obtryx is designed to be placed close to the pudendal nerve and caused JANET FEARRINGTON pudendal neuralgia.

67. The Obtryx is designed to be placed close to the obturator nerve and caused JANET FEARRINGTON obturator neuralgia.

68. The Obtryx was designed to be placed into the groin causing hip adductor myalgia.

69. The Obtryx, Advantage Fit, and the Polyform Synthetic Mesh were designed to be placed on or about the pelvic floor piercing muscles of the pelvic floor causing tension pelvic floor myalgia.

70. The Obtryx and Advantage and the Polyform Synthetic Mesh were designed to be placed on or about the pelvic floor adjacent to the vagina, the urethra, the bladder, and the rectum causing pelvic floor myalgia, painful bladder filling, chronic pelvic pain, impaired mobility, impaired sexual function, dyspareunia, impaired bladder function, recurrent infections, recurrent incontinence, impaired bowel function, and impaired mobility related to chronic inflammatory response, scar plate formation, adhesions, and erosions and migration of the Products.

71. The Obtryx is designed to require blindly placing the arms of the sling into the hip adductor muscles and through the obturator foramen and does not account for anatomic variations of the pudendal nerve and obturator nerve.

72. The Defendant did not study the anatomic variations now known for the pudendal and obturator nerve.

73. The Obtryx, Advantage Fit, and Polyform Synthetic Mesh were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, and bladder function. These product changes occurred as the Obtryx, Advantage Fit, and Polyform Synthetic Mesh implanted in JANET FEARRINGTON were degraded on explant.

74. The Obtryx, Advantage Fit, and Polyform Synthetic Mesh were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull, cause fibrosis of muscles, adhesions between tissues, and

inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain. These changes occurred as the Obtryx, Advantage Fit, and Polyform Synthetic Mesh were implanted in JANET FEARRINGTON and at explant were degraded.

75. JANET FEARRINGTON has impairment that includes the following diagnoses: dyspareunia, impaired gait secondary to spasms of the right and left obturator internis, pelvic floor tension myalgia, vaginal and vulva allodynia, anorectal pain, recurrent incontinence, recurrent urinary tract infection, bowel and bladder dysfunction, chronic cystitis, interstitial cystitis, vaginal erosion, hip adductor myalgia, pudendal neuralgia, obturator neuralgia, complex regional pain syndrome as a result of having Defendant's Obtryx, Advantage Fit, and Polyform Synthetic Mesh implanted in her body.

76. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Obtryx, Advantage Fit, and Polyform Synthetic Mesh for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

77. Had Defendant properly disclosed the risks associated with the Obtryx, Advantage Fit, and the Polyform Synthetic Mesh for transvaginal use, Plaintiff would not have agreed to treatment with these devices.

78. The injuries suffered by Plaintiff were caused by the wrongful acts, omissions, and fraudulent representations of Defendant.

79. As a result of having the Obtryx, Advantage Fit, and Polyform Synthetic Mesh implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury including pudendal neuralgia, obturator neuralgia, pelvic floor

tension myalgia, hip adductor myalgia, complex regional pain syndrome, erosion, recurrent urinary tract infections, interstitial cystitis, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain, and has undergone medical treatment, multiple surgical procedures related to failure of the device and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

FIRST CAUSE OF ACTION

[Strict Liability – Failure to Warn]

80. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

81. Defendant manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiff's healthcare providers to be used for the treatment of stress urinary incontinence and/or pelvic organ prolapse.

82. Defendant's manufacturing process and the raw materials used for Defendant's Pelvic Mesh Products resulted in product defects.

83. At all times mentioned herein, the Pelvic Mesh Products were and are dangerous and presented a substantial danger to patients who were implanted with the Pelvic Mesh Devices, and these risks and dangers were known or knowable at the time of distribution and implantation in the Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed to pelvic reconstruction patients because its uses were specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used in a way reasonably foreseeable to Defendant by Plaintiff and Plaintiff's healthcare

providers. Defendant failed to provide warnings of such risks and dangers to Plaintiff as described herein.

84. Plaintiff would not have consented to use Defendant's Pelvic Mesh Products had Defendant given adequate warnings to Plaintiff and Plaintiff's implanting physicians.

85. As a result of the implantation of the Pelvic Mesh Products, Plaintiff suffered debilitating injuries including pudendal neuralgia, catastrophic pain syndrome, obturator neuralgia, complex regional pain syndrome, pelvic floor tension myalgia, dyspareunia, recurrent urinary tract infection, permanent disfigurement, hip adductor myalgia, anorectal pain, erosion, bowel and bladder dysfunction, loss of mobility, and the need for additional surgery and therapeutic treatments..

86. In doing the acts herein described, the Defendant acted with oppression, fraud and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendant and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendant.

87. At all times herein mentioned, the Pelvic Mesh Products were being used as intended by Defendant and in a manner foreseeable to Defendant.

88. As a result of the defective condition of the Pelvic Mesh Products, and the lack of sufficient warnings, Plaintiff has suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

SECOND CAUSE OF ACTION

[Strict Liability – Manufacturing Defect]

89. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

90. At all times herein mentioned, Defendant's Pelvic Mesh Products were prescribed and used as intended by Defendant and in a manner reasonably foreseeable to Defendant.

91. The Pelvic Mesh Products were defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time they left the possession of the Defendant, in that, and not by way of limitation, the products differed from the Defendant's intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

92. As a proximate and legal result of the defective condition of the Pelvic Mesh Products, Plaintiff was caused to suffer and will continue to suffer the herein described injuries and damages.

WHEREFORE, said Plaintiff pray for judgment against Defendant as hereinafter set forth.

THIRD CAUSE OF ACTION

[Strict Liability – Design Defect]

93. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

94. The Pelvic Mesh Products were designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, licensed, distributed, wholesaled, and sold by Defendant.

95. The Pelvic Mesh Products manufactured, licensed, supplied, and/or placed into the stream of commerce by Defendant were defective and unreasonably dangerous in that:

a. The foreseeable risks exceeded the benefits associated with the Product design or formulation;

b. They contained inadequate post-marketing warnings or instructions; and

c. They were more dangerous than would be expected or appreciated by an ordinary consumer.

96. The Pelvic Mesh Products that were manufactured, supplied, and/or placed into the stream of commerce by Defendant were more dangerous than an ordinary customer would expect, and more dangerous than other Products or procedures available to treat stress urinary incontinence, pelvic organ prolapse and/or rectocele repair.

97. The design defects in Defendant's Products existed at the time when the Products left Defendant's control.

98. Defendant knew that the Products were to be purchased and used without inspection for defects.

99. The Pelvic Mesh Products were and are unsafe for their intended and foreseeable uses by reason of defects in the design so that the Products would not safely serve their purpose, but would instead expose the users of the Pelvic Mesh Products to incur serious injuries.

100. Plaintiff used the Products in a reasonably foreseeable manner.

101. Defendant designed the Products defectively, causing the Products to fail to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

102. As a direct and proximate result of the aforementioned defects in the design of the Products, Plaintiff sustained the injuries and damages set forth herein.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

FOURTH CAUSE OF ACTION

[Negligence]

103. Plaintiff re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

104. At all times herein mentioned, Defendant was and is engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Pelvic Mesh Products.

105. Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendant breached said duty of care.

106. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to promotion, advertising, sale, and safety monitoring of the Products, and to adequately test and warn of the risk and dangers of the Product, both before and after sale.

107. Additionally, Defendant owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous

propensities of the Products manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Products to perform as intended or as an ordinary consumer would expect.

108. At all times relevant hereto, Defendant breached the aforementioned duties in that it negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted and advertised the Pelvic Mesh Products in that said Products caused, directly and proximately, the injuries of Plaintiff through failure of the Products to perform as intended or as an ordinary consumer would expect.

109. Defendant's manufacturing process and the raw materials used for Defendant's Pelvic Mesh Products resulted in product defects.

110. The acts of Defendant constitute violations of the duty of ordinary care and skill owed by Defendant to Plaintiff.

111. Plaintiff used and was implanted with Defendant's Products referred herein in a manner that was reasonably foreseeable.

112. As the direct and proximate result of Defendant's breach of its aforementioned duties with respect to the Products, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

FIFTH CAUSE OF ACTION

[Breach of Implied Warranty]

113. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

114. Defendant impliedly warranted to the Plaintiff, her prescribing physicians and healthcare providers, the medical scientific, pharmaceutical and health communities, the FDA, and the public, in general, that the Products were of merchantable quality and safe and fit for the use for which the Products were intended.

115. Plaintiff and her physicians and healthcare providers were, and remain, unskilled in the research, design and manufacture of the Products and reasonably relied on the skill, judgment and implied warranty of Defendant in using the aforementioned Products.

116. Defendant breached its warranties in that the Products were neither safe for their intended use nor of merchantable quality, as warranted by Defendant, in that the Products had dangerous propensities and known or knowable side effects when put to their intended use and would cause severe injuries to the user, which propensities and side effects were known or knowable but were not warned of by Defendant.

117. As a result of the aforementioned breach of implied warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

118. After Plaintiff was made aware her injuries were a result of the aforesaid Products, Defendant had ample and sufficient notice of breach of said warranty.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

SIXTH CAUSE OF ACTION

[Breach of Express Warranty]

119. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

120. Defendant expressly warranted to Plaintiff and/or their authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that the defective Pelvic Mesh Products were safe, effective, fit and proper for their intended use.

121. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendant, and upon said express warranty, in using the aforesaid Pelvic Mesh Products. The warranty and representations were untrue in that the product caused severe injury to Plaintiff and were unsafe and, therefore, unsuited for the use in which they were intended and caused Plaintiff to sustain damages and injuries herein alleged.

122. As soon as the true nature of the Pelvic Mesh Products, and the fact that the warranty and representations were false, were ascertained, said Defendant had ample and sufficient notice of the breach of said warranty.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

SEVENTH CAUSE OF ACTION

[Fraud]

123. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

124. Defendant falsely and fraudulently represented to Plaintiff, her physicians, and to members of the general public that the aforesaid Products were safe, effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. The representations by said Defendant were, in fact, false. The true facts include, but are not limited to, that the aforesaid Products were not safe to be used for treatment of urinary incontinence, and pelvic organ prolapse, and were, in fact, dangerous to the health and body of Plaintiff.

125. When the Defendant made these representations, it knew that they were false. Defendant made said representations with the intent to defraud and deceive Plaintiff, and with the intent to induce Plaintiff to act in the manner herein alleged, that is, to use the aforementioned Products for treatment of urinary incontinence and pelvic organ prolapse.

126. At the time Defendant made the aforesaid representations, Plaintiff took the actions herein alleged; Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid Products as herein described. If Plaintiff had known the facts regarding the safety of the Products, she would not have taken such action. The reliance of Plaintiff and her physicians upon Defendant's representations were justified because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

127. As a result of Defendant's fraud and deceit, Plaintiff was caused to sustain the herein described injuries and damages.

128. In doing the acts herein alleged, the Defendant acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendant and others from

engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendant.

129. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the Pelvic Mesh Products as described herein. Defendant did not disclose this information to the Plaintiff, her healthcare providers, the health care community and the general public. Without full knowledge of the dangers of the Pelvic Mesh Product Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

130. As a direct and proximate result of Defendant's fraud, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, said Plaintiff pray for judgment against Defendant as hereinafter set forth.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

131. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

132. Defendant from the time that the Pelvic Mesh Products were first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to the Plaintiff, her prescribing physicians and

healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, including, but not limited to, the misrepresentation that the Pelvic Mesh Products were safe, fit, and effective for the treatment of pelvic organ prolapse, stress urinary incontinence, and/or rectocele repair.

133. At all times relevant hereto, Defendant conducted a sales and marketing Campaign to promote the sale of the Pelvic Mesh Products and willfully deceived the Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of the Pelvic Mesh Products.

134. Defendant made the foregoing misrepresentations without any reasonable ground for believing them to be true. These misrepresentations were made directly by Defendant, by sales representatives, detail persons and other authorized agents of said Defendant, and in publications and other written materials directed to the Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general with the intention of inducing reliance and the purchase and implantation of the Pelvic Mesh Products.

135. The foregoing representations by Defendant were in fact false in that the Pelvic Mesh Products are not, and at all relevant times alleged herein, were not safe, fit, and effective for the treatment of pelvic organ prolapse, stress urinary incontinence and/or cystocele, the use of the Pelvic Mesh Products is hazardous to health, and the Pelvic Mesh Products have a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described herein by Plaintiff. The foregoing misrepresentations by Defendant were made with

the intention of inducing reliance and inducing the purchase and implantation of Pelvic Mesh Products.

136. In reliance on the misrepresentations of Defendant, Plaintiff and her prescribing physicians and healthcare providers were induced to purchase and use the Pelvic Mesh Products. If they had known of the true facts and the facts concealed by Defendant, they would not have used the Pelvic Mesh Products, and their reliance upon Defendant's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

137. As a result of the concealment of the facts set forth above, Plaintiff sustained injuries as set forth herein.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

NINTH CAUSE OF ACTION

[Fraud by Concealment]

138. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

139. At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the Pelvic Mesh Products, that is, that said Products were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely they were to cause serious consequences to users including permanent and debilitating injuries. Defendant made the affirmative representations as set forth above to Plaintiff and her physicians and the general public prior to the date the Pelvic Mesh Products were implanted in Plaintiff, while concealing material facts.

140. At all times herein mentioned, Defendant willfully and maliciously concealed facts as set forth above from Plaintiff and her physicians, with the intent to defraud as herein alleged.

141. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for correction of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele. Defendant's misrepresentations were a substantial fact in Plaintiff agreeing to utilize the Pelvic Mesh Products for correction of her medical conditions.

142. As a result of the concealment of the facts set for the above, Plaintiff sustained injuries as set forth herein.

143. The herein-described conduct of said Defendant was willful, malicious, fraudulent, outrageous and in conscious disregard and indifference to the safety and health of patients with pelvic medical conditions, such as stress urinary incontinence or pelvic organ prolapse. Plaintiff, for the sake of example and by way of punishing said Defendant, seeks punitive damages according to proof.

WHEREFORE, said Plaintiff prays for judgment against Defendant as hereinafter set forth.

PUNITIVE DAMAGES

144. At the time Defendant designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Products and failed to adequately warn Plaintiff of the dangerous and defective nature of the Products and thereby caused Plaintiff's injuries, Defendant knew, or in the exercise of the appropriate degree of care should have known, that its conduct

created a high degree of probability of injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and prays for judgment against Defendant as follows:

1. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
2. For past and future economic and special damages, according to proof at the time of trial;
3. For past and future medical and incidental expenses, according to proof at the time of trial;
4. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;
5. For past and future mental and emotional distress, according to proof at the time of trial;
6. For costs, attorneys fees, interest, or any other relief, monetary or equitable, to which she is entitled;
7. For punitive and exemplary damages in an amount to be determined at trial;
8. For injunctive relief, enjoining Defendant from the acts of unfair competition and untrue and misleading advertising;
9. For a disgorgement of profits, according to proof at the time of trial;
10. For such other and further relief as the Court may deem just and proper.

Respectfully submitted,

MARTIN BAUGHMAN, PLLC

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